K011946

newdeal
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AUG 2 4 2001

3. SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION:

NewDeal SA
Parc d'Activitiés Garigliano
Rue de la Convention
38 200 VIENNE
FRANCE
Tél. : (33) 4 74 78 15 15
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B. ESTABLISHMENT REGISTRATION NUMBER: 9615741

C. OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph. D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac , MD 20854
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estrin@yourFDAconsultant.com

D. DATE OF PREPARATION OF THIS SUMMARY: June 20, 2001

E. PROPRIETARY (TRADE) NAME: **SPIN® SNAP-OFF SCREW**

F. COMMON NAME: Bone fixation screw,
Self drilling and self tapping snap-off screw

G. CLASSIFICATION NAME AND REFERENCE

Smooth or threaded metallic bone fixation fastener (21 CFR, Section 888.3040)

H. PROPOSED REGULATORY CLASS: Class II

I. **DEVICE PRODUCT CODE:** 87HWC

J. **PANEL CODE:** 21 CFR par. 888.3040

K. **DESCRIPTION OF DEVICE:**

The **SPIN® SNAP-OFF SCREW** is self drilling and self tapping snap-off screw. One part is fixed on a standard surgical power equipment and when the snap-off screw is totally introduced in the bone, its head is blocked and the breaking torque is important enough to cause dissociation between the screw and the snap-off. It comes in lengths from 11 to 14 mm. The length varies whereas the head diameter is constant (2 mm) and the distal thread length is 7 mm to 10 mm.

L. **INTENDED USE:**

The **SPIN® SNAP-OFF Screw** is intended to be implanted for fixation of bone fractures or for bone reconstructions.

M. **INDICATIONS FOR USE:**

The "new" **SPIN® SNAP-OFF SCREW** is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Fixation of small bone fragments.
- Weil osteotomy
- Mono-cortical fixation
- Osteotomies and fractures fixation in the foot and hand

N. **PREDICATE DEVICE:**

The **"new" SPIN® SNAP-OFF SCREW** is technically equivalent to the **SPIN® SNAP-OFF** screw currently approved (K991477). The "new" **SPIN® SNAP-OFF SCREW** is substantially equivalent to the Depuy **Twist-off Screw** (K962233), the howmedica **Luhr Screw system** (K950595), the 2.0mm and 2.4mm Synthes **Cortex Screw** (K952272and K002271) and the **Osteomed M3 Screw** (K924018, K924138).

O. **COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:**

The **"new" SPIN® SNAP-OFF screw** is technically equivalent to the device currently cleared. They have the same intended use, and the design of the active part (screw itself) has not changed. The **"new" SPIN® SNAP-OFF screw**, the Depuy **Twist-off Screw**, the howmedica **Luhr Screw system**, the 2.0mm and 2.4mm Synthes **Cortex Screw** and the **Osteomed M3 Screw** have the same intended use and all are indicated for fixing small fractures or osteotomies. All are made from Titanium alloys, except the Luhr Screw system which is provided in Cobalt-Chrome alloy, and the 2.4mm Synthes Cortex Screw which is provided in 316L Stainless steel. The Titanium alloy used for the **SPIN® SNAP-OFF SCREW** is a material commonly used among professionals in the orthopedic field. The **"new" SPIN® SNAP-OFF screw**, the Depuy **Twist-off Screw**, the howmedica **Luhr Screw system**, the 2.0mm Synthes **Cortex Screw** and the **Osteomed M3 Screw** are 2.0mm diameter screws (range 1.2 – 3.0mm for the M3 screw system). Most have a low profile head, are self-drilling and self-tapping screws.

P. **SUMMARY OF STUDIES:**

Rupture torque of the "new" **SPIN® SNAP-OFF SCREW** is the same as for the [illegible] approved, as the design of the active part (screw itself) has not changed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2001

New Deal, S.A.
C/O Norman F. Estrin, Ph.D.
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K011946
Trade Name: The Spin Snap-Off Screw
Regulation Number: 888.3040
Regulatory Class: Class II
Product Code: HWC
Dated: June 20, 2001
Received: June 21, 2001

Dear Dr. Estrin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011946

Device Name: **SPIN® SNAP-OFF SCREW**

Indications for Use:

The "new" **SPIN® SNAP-OFF SCREW** is indicated for fixation of bone fractures or for bone reconstruction.

Examples include:
- Fixation of small bone fragments.
- Weil osteotomy
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011946

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